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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,314	01/08/2002	Manmohan Singh	PP01572.102	2216

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EXAMINER
HILL, MYRON G

ART UNIT 1648	PAPER NUMBER
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DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,314

Applicant(s)

SINGH ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/28/04
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 4, 7- 22, and 29- 43 is/are pending in the application.
- 4a) Of the above claim(s) 15- 22, 29- 32, 35, 38, 39, and 44- 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 4, 7- 14, 33, 34, 36, 37, and 40- 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This action is in response to paper filed 28 June 2004. Claims 33- 46 have been added.

Election/Restrictions

Newly submitted claims 33- 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are drawn to methods that were restricted out in the Lack of Unity and to species that were restricted out of the original composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35, 38, 39, and 44- 46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 33, 34, 36, 37, and 40- 43 will be considered to the extent that they read on the elected invention.

Claims 5, 6, 15- 32, 35, 38, 39, and 44- 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims x.

Rejections Maintained

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 7, and 9- 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Duncan *et al.* (WO 94/20070).

The claims are drawn to a composition comprising at least one of each of a bioadhesive, an adjuvant, and an antigen.

Applicant argues that Duncan *et al.* do not disclose the components of the now claimed invention in the order recited in the claims and cite case law that a reference must contain all elements of the claimed invention and case law that the elements must be arranged in the order as claimed.

Applicant's arguments have been considered and not found persuasive.

The recited elements of the now claimed composition are disclosed in Duncan *et al.* (see prior rejection). The case law cited for specific order not apply in this case for a composition. The cited cases refer to suspension systems (*Richardson v. Suzuki*) which is a mechanical device and not analogous to a composition and hair curler/detangler type devices (*Connell v. Sears*) another mechanical device which is not analogous to a composition and the case seems to deal more with validity and enforcement not anticipation. A composition requires that the components be there. A method of making or using the composition may require that products are used or mixed in a particular order but this does not apply here.

The limitation of “adapted for intranasal delivery” does not change the structure of the composition and is treated as an intended use of the composition which in itself does not add patentable weight to the composition. However, Duncan *et al.* do teach nasal administration of compositions (page 10, line 22) as an intended site for administration of the pharmaceutical composition.

Thus, the rejection over Duncan *et al.* is maintained.

Rejection Modified Because of Amendment

Claim Rejections - 35 USC § 103

Claims 1, 7, 8, 33, 34, 36, 37, and 40- 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan *et al.* and Giuliani *et al.*

The claims are drawn to a composition comprising at least one of each of a bioadhesive, an adjuvant comprising a mutant detoxified bacterial ADP-ribosylating toxin, and an antigen.

Duncan *et al.* teaches a composition comprising an antigen, an adjuvant, and a bioadhesive as discussed in the rejection in the prior Office Action. Duncan *et al.* teach the advantage of bacterially derived adjuvants (Examples 6 and 7).

Duncan *et al.* do not teach LT-R 72.

Giuliani *et al.* teach a modified *E. coli* enterotoxin that has improved properties over wild type enterotoxin, LT-R72 (abstract).

One of ordinary skill in the art at the time of invention would have been motivated to use the adjuvant of Giuliani *et al.* because they teach that it is a mucosal adjuvant, that it is less toxic than wild type and would expect it to work as an adjuvant because it has high adjuvanticity and is shown to function as an adjuvant. One of ordinary skill in the art at the time of invention would have expected the LT-R72 of Giuliani *et al.* to have better results than the bacterial adjuvant of Duncan *et al.* because the LT-R72 of Giuliani *et al.* is taught to be more active and thus a better adjuvant.

Applicant argues that the prior art of Duncan *et al.* do not obtain the same better results as the disclosed in the specification and in fact teach diminished results when compared to poly(acrylic acid).

Applicant's arguments have been fully considered and not found persuasive.

While it is true that unexpected results can teach away from obviousness, the compositions compared are not the same. The composition of the combination of the prior art references is not used in the Duncan *et al.* Furthermore, there is motivation to combine the prior art with the expectation of improved results because Giuliani *et al.* teach that the modified bacterial adjuvant works better than the wild type.

Thus, it would have been *prima facie* obvious to modify the composition of Duncan *et al.* with the adjuvant of Giuliani *et al.* with the expectation of success of making a more immunogenic composition.

Conclusion


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No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Myron G. Hill
Patent Examiner
29 August 2004


JAMES HOUSEL 8/23/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600